

NSW Poisons Information Centre
www.poisonsinfo.nsw.gov.au

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Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

**Re: Proposed amendments to the Poisons Standard – ACMS and Joint
ACMS/ACCS meetings, June 2020**

The NSW Poisons Information Centre (NSW PIC) provides a phone-based advice service on suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

1.1 Oxymetazoline

Calls to the NSW PIC regarding exposures to oxymetazoline nasal sprays have remained constant over the past 6 years, averaging 48 calls per year. Of these calls, 68% related to therapeutic errors and children were involved in almost 80% of total calls. Around 15% calls involving oxymetazoline nasal spray involved the patient either being at or referred to a medical practitioner or hospital. This high percentage of therapeutic error calls shows patients do not easily understand labelling and that parents are frequently administering these products incorrectly to their children. Our concern is that if these products were available for general purchase (unscheduled) the incidence of error would increase. We also believe the availability of oxymetazoline nasal sprays for general purchase (unscheduled) would potentially allow therapeutic misuse to continue for a longer period without opportunity for intervention by a pharmacist. More than 5 sprays intranasally or an ingestion of just 1ml of 0.05% solution of oxymetazoline can cause symptoms such as drowsiness, hypotension, bradycardia, peripheral vasoconstriction and dyspnoea in a young child. We are also concerned that the perception of risk to children would be reduced if these products were available for general purchase.

1.2 Eletriptan

The NSW PIC does not support the proposed change to scheduling of eletriptan. We regularly receive calls regarding exposures to triptan medications, and although not large in numbers, these calls are very likely to be symptomatic and require medical treatment. Eletriptan is no different, with over 50% of exposures developing symptoms and requiring further assessment in hospital. The ability of triptans to interact with other medications and existing medical conditions is likely to contribute to this increased incidence of symptomatic adverse reactions and poisoning exposures. Wider availability as a schedule 3 product will see an increased use of triptans in the community and growth in the numbers of adverse reactions and poisoning exposures. The very real possibility exists that these exposures will increase disproportionately to usage as community awareness grows and patients begin self-prescribing. Current regulations which allow for emergency supply to patients who have a clear history of dispensing are sufficient to ensure those patients in need are

able to safely access their regular medication in times of need without increasing risk to the community.

1.3 Clotrimazole

The proposed scheduling change for clotrimazole “in preparations for vaginal use containing 1 per cent or less of clotrimazole” to Schedule 2 does not pose an increased poisoning risk, however, as pharmacists we feel this change may potentially allow therapeutic misuse to continue for a longer period without opportunity for intervention by a pharmacist.

1.4 Sildenafil

The NSW PIC does not support the proposed change to Schedule 3 for “SILDENAFIL in divided preparations for oral use containing 50 mg of sildenafil per dosage unit in packs of not more than 4 dosage units in accordance with the requirements of Appendix M.”

Calls to the NSW PIC regarding exposures to sildenafil have remained fairly constant over the past 6 years, averaging 36 calls per year. 65% of these calls involved a patient who was either in or referred to hospital. Of these 33% were accidental paediatric exposures and 17% were deliberate self-poisoning. 50% of all calls were due to either therapeutic error or adverse effects following therapeutic use. Many of these calls were a result of patients developing symptoms after taking more than the recommended dose either all at once or over a period of time and some calls involved patients for whom the medication had not been prescribed.

Common adverse effects include headache, dizziness (due to hypotension), flushing, tachycardia, palpitations, chest pain and priapism. Patients with pre-existing cardiovascular disease are at much greater risk of developing serious side-effects. Exceeding the recommended dosage is also associated with serious side-effects. Our concern is that if sildenafil is available without a prescription the risk of therapeutic error, therapeutic misuse and inappropriate use in patients with risk factors may increase.

1.5 Ibuprofen

The NSW PIC does not support the proposed schedule change to Schedule 2 of ibuprofen “in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units, when labelled: i) not for the treatment of children under 12 years of age.” Our concern is that without pharmacist intervention the risk of dosing error is considerable and whilst a one-off error may be well-tolerated repeat errors may result in adverse gastrointestinal and renal effects. The number of calls received regarding therapeutic dosing errors of 400mg ibuprofen has been steadily increasing and more than tripled in 2019. Whilst these call numbers are still low we are concerned they will steadily increase if 400mg ibuprofen is made available without consultation with a pharmacist. NSW PIC has seen a significant increase in calls regarding therapeutic dosing errors of a combination paracetamol/ibuprofen product which also has a therapeutic dose of only one tablet.

Year	Calls to NSW PIC regarding Ibuprofen 400mg therapeutic dosing errors	Calls to NSW PIC regarding Paracetamol 500mg/ Ibuprofen 200mg therapeutic dosing errors
2015	9	-
2016	10	31
2017	12	102
2018	11	166
2019	34	192
Jan-April 2020	8	56

1.6 Cumyl-pegacalone

The NSW PIC strongly supports the proposal that a new Schedule 9 entry be created for cumyl-pegacalone.

